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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/056,473

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Jude S. Sauer

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

NOTIFICATION DATE

DELIVERY MODE

02/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/056,473	SAUER, JUDE S.	
	Examiner	Art Unit	
	LINDSEY BACHMAN	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-13,20,21,23-40,42-45 and 51-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-13,20,21,23-40,42-45 and 51-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the appeal brief filed on 13 May 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/s/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "the handle body portion". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13, 53-56, 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauer et al. (US Patent 5,431,666).

Claim 11: Sauer discloses a device that contains a tongue member (37b) having a distal section insertable into a wound and an opening (the opening in 37b is unlabeled, but it is clear from the drawings that there is an opening used to accommodate elements 16, 18). The device also contains a face (distal face of grooves 40, 42 next to element 44. This face can be seen in Figures 2 and 12-14 - it is unlabeled) separated from the tongue by a gap (44). The device further contains a

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sleeve holder that holds sleeves (16, 18) disposed within the sleeve holder (see Figure 2). The sleeves are joined by suture material (20).

Claim 12, 13: Sauer discloses a device that contains a tongue member (37b) having a distal section insertable into a wound. The device also contains a face (distal face of grooves 40, 42 next to element 44. This face can be seen in Figures 2 and 12-14 - it is unlabeled) separated from the tongue by a gap (44). The device further contains a guidewire tube (40) disposed through an elongate body assembly (37). The distal end of the guidewire tube is next to an opening in the tongue member (the opening in 37b is unlabeled, but it is clear from the drawings that there is an opening used to accommodate elements 16, 18).

Claim 53, 54: Sauer discloses a tip for a surgical apparatus that contains a window (44), a first wall (distal face of grooves 40, 42 next to element 44. This face can be seen in Figures 2 and 12-14 - it is unlabeled) at an angle to the longitudinal axis and a second wall (proximal face of 37b) having a tongue (37b) with an opening (unlabeled but used to hold ferrules 16, 18). The base of the tongue forms the bottom portion of the window (see Figure 2).

Claim 55, 56: The proximal end of the tongue forms a T-shaped extension (the two needle holders 40, 42 are formed as grooves in element 37 - this creates a T-shaped extension as shown in Figure 2).

Claim 53 (alternate rejection), 58: Sauer discloses a device that contains a window (opening of region 34 in Figure 2), a first wall (face of element 32), a second wall (proximal face of element 30b-shown in Figure 2) and a tongue (34) that forms a

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bottom portion of the window. The tongue contains a longitudinal opening (element 30 is a tube) with an opening at the distal end that is proximal to the distal end of the tip (opening at 30b is used to accommodate element 37b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 51 and 5-10, 20, 21, 23-39, 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer'666.

Claim 51, 52: Sauer teaches a device that contains a window (opening at 44); a first wall (distal face of grooves 40, 42 next to element 44. This face can be seen in Figures 2 and 12-14 - it is unlabeled); a second wall (proximal face of 37b) having a ferrule holder (opening in 37b holds ferrules 16, 18 as shown in Figure 2) and a tongue (44) extending between the first and second walls.

Sauer'666 discloses the claimed invention except Sauer'666 does not teach that the ferrule holder is separable from the tongue. The Sauer'666 device would work in the same way if the ferrule holder were separable from the tongue. It would have been obvious to one having ordinary skill in the art at the time the invention to make the ferrule holder separable from the tongue, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. and MPEP 2144.04.

Claim 5, 6, 7, 8: Sauer further teaches that the device contains an elongate body assembly (37) connecting a body portion (12) to the tongue member (44). The device further contains two elongate needles (36, 38) positioned within the elongate body assembly (in grooves 40, 42) (column 5, lines 20-36). The first and second needles is movable by a first and second levers (70, 72 respectively) (column 6, lines 38-44).

Claim 9: Sauer teaches a body portion (12) having first and second levers (160, 162) pivotally secured to the body portion (via element 164, see Figures 5-6) connected with the first and second needles (column 8, lines 4-14). Sauer does not disclose the use of multiple colors to identify which lever is interacting with which needle. However, the concept of color-coding is well known in the art. Patentability cannot be predicated on color-coding a surgical device. The color-coding so as to identify which needle each handle is operating would have been entirely obvious. Further, applicant has not shown any functional criticality for color-coding the levers. The device will perform the same way regardless of the color.

Claim 10: Sauer teaches a body portion (12) having first and second levers (160, 162) pivotally secured to the body portion (via 164, see Figures 5-6). The first and second levers are mounted to the distal end of the body portion (see Figures 1, 5 and 6).

Claim 20, 21: Sauer teaches a body portion (12); a tubular portion (170) attached to the distal end of the body; and a lever (172) having a distal end operatively coupled to the distal end of the body portion. The lever is parallel to the longitudinal axis in the closed position (see Figure 5).

Claim 23: Sauer teaches a body portion (12); a tubular portion (170) attached to the distal end of the body; and a lever (172) having a distal end operatively coupled to the distal end of the body portion. The device further contains a first and second link (36a, 38a) connected to the lever at one end and to first and second slidable member (70 and 72) at the other end of the link. The slidable members move within the body portion (see Figures 5 and 6).

Claim 24: Movement of the lever towards the proximal end of the body portion causes one slidable member to move towards the distal end of the body portion and the other slidable member to move away from the distal end of the body portion (column 8, lines 26-58).

Claim 25, 26: Sauer discloses a drive block (106) in which the slidable member cooperates with the drive block to move the drive block with the slidable member (column 11, lines 12-30).

Claim 27, 29: The drive block is biased with a spring (118, 120) (column 7, lines 23-28).

Claim 28: The drive block contains a longitudinal opening (see Figure 4 or 8).

Claim 23 (alternate rejection), 39: Sauer teaches a body portion (12); a tubular portion (170) attached to the distal end of the body; and first and second levers (160, 162) having a distal end operatively coupled to the distal end of the body portion. The device further contains first and second link (36a, 38a) connected to the lever at one end and to first and second slidable member (70 and 72) at the other end of the link. The slidable members move within the body portion (see Figures 5 and 6).

Claim 30, 31, 33, 34, 35, 36, 37: Movement of the lever towards the proximal end of the body portion causes one slidable member to move towards the distal end of the body portion and the other slidable member to move away from the distal end of the body portion (column 8, lines 26-58). The slidable members (70, 72) are needle drivers.

Claim 32: The needles are disposed within the tubular portion (Figures 10, 11).

Claim 42, 43, 44: Sauer teaches a body portion (12), a tubular portion (30) and first and second levers (160, 162) pivotally secured to the body portion (via element 164, see Figures 5-6) connected with the first and second needles (column 8, lines 4-14).

Regarding claim 45, Sauer does not disclose the use of multiple colors to identify which lever is interacting with which needle. However, the concept of color-coding is well known in the art. Patentability cannot be predicated on color-coding a surgical device. The color-coding so as to identify which needle each handle is operating would have

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been entirely obvious. Further, applicant has not shown any functional criticality for color-coding the levers. The device will perform the same way regardless of the color.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green, et al. (US Patent 5,425,745).

Green'745 teaches a surgical apparatus containing a body portion (102) having a distal end (105) and a proximal end (towards 117); a tubular portion (124) having a distal end (137) and a proximal end (105), wherein the proximal end of the tubular portion is connected to the distal end of the body portion; and a lever (104) having a distal end (105) and a proximal end (towards 107), the distal end of the lever coupled to the distal end of the body portion. A flat surface of the lever lies substantially flush with body portion in a closed position of the lever (see Figure 1). Green'745 does not teach that the cross-section of the lever is U-shaped. However, this is no criticality of this feature and the Green'745 device would perform equally as well if the cross-section of the device were U-shaped. Further, it would be obvious to change the shape of the handle in order to make it easier for the user to grip.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer'666.

Claim 57: Sauer'666 discloses the claimed invention except Sauer'666 does not teach that the ferrule holder is separable from the tongue. It would have been obvious to one having ordinary skill in the art at the time the invention to make the ferrule holder separable from the tongue, since it has been held that constructing a formerly integral

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structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. and MPEP 2144.04.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

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Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773